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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,757	10/26/2006	Jonathan Andrew Fuller	ISA-168.01	1524

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EXAMINER	
XU, XIAOYUN	
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1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,757	FULLER ET AL.	
	Examiner	Art Unit	
	ROBERT XU	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment and RCE request filed on 05/11/2009 has been entered and fully considered. Claims 26-72 are pending, of which Claims 26, 40, 54, 62 and 63 are amended, claims 71 and 72 are new.

Response to Amendment

2. In response to amendment, the examiner withdraw 35 USC 112 second paragraph rejection and modifies rejection over the prior art established in the previous Office action.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. **Claims 26, 27, 29-41, 43-59, 61 and 63-72** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US Patent No. 6,200,532) (Wu).

In regard to Claim 26, Wu discloses a device for performing blood coagulation assay, particularly prothrombin times and activated partial thromboplastin times (see abstract). The device comprises a disposable strip containing a chamber for holding a quantity of blood sample, a magnetic bender body in the chamber and a magnetic field generator underneath the chamber (see abstract, Col. 5, lines 29-36, 62-67). The first magnetic field causes the magnetic bender body to move in a first direction within the chamber through uncoagulated liquid, and the second magnetic field causes the body to move in a second direction within the chamber through uncoagulated liquid (see Col. 5, line 1-6).

Wu discloses that the magnetic bender body in the chamber is attached onto a piezoelectric film which is fixably attached at one end to the chamber wall (see Figure 2). Which is an obvious variation to "a body disposed in the chamber but not fixably attached to the chamber" as recited in the instant claim.

Wu discloses one magnetic device which generates two magnetic fields (see Col. 5, line 1-6, Figure 2). This is an obvious variation to "the first and second magnetic

device being arranged in use to provide first and second magnetic fields" as recited in the instant claim.

In regard to Claim 27, Wu discloses that through the attachment of the piezo film to the magnetic bender, movement of the magnetic bender body is detected by measuring electric signal generated at the piezo film characterized by its frequency and amplitude due to movement of the attached metal film (see Col. 5 lines 12-16).

In regard to Claim 54, Wu discloses a method for performing blood coagulation assay, particularly prothrombin times and activated partial thromboplastin times (see abstract). The method comprises steps of providing a blood sample in a disposable strip containing a chamber, and applying magnetic field to the chamber (see abstract, Col. 5, lines 29-36, 43-45). The first magnetic field causes the magnetic bender body to move in a first direction within the chamber through uncoagulated liquid, and the second magnetic field causes the body to move in a second direction within the chamber through uncoagulated liquid (see Col. 5, line 1-6).

As has been discussed in regard to Claim 26, Wu discloses that the magnetic bender body in the chamber is attached onto a piezoelectric film which is fixably attached at one end to the chamber wall (see Figure 2). This is an obvious variation to "a body disposed in the chamber but not fixably attached to the chamber" as recited in the instant claim.

Wu discloses one magnetic device which generates two magnetic fields (see Col. 5, line 1-6, Figure 2). This is an obvious variation to "the first and second magnetic device being arranged in use to provide first and second magnetic fields" as recited in the instant claim.

In regard to Claim 30, Wu discloses that the chamber is formed in a disposable strip (see Col. 5, lines 62-67; Col. 6, line 1-4).

In regard to Claim 31, Wu discloses that the chamber having the magnetic bender body is elongated and has substantially uniform cross-section (see Figure 1 and 2).

In regard to Claim 38, Wu teaches that the bender body comprises an iron-based material, which experiences a force when placed in a magnetic field (see Col.4, lines 60-63).

In regard to Claims 39 and 61, Wu discloses that a clotting reagent is disposed in the chamber (see Col. 5, lines 38-42).

In regard to Claims 40 and 63, Wu discloses a device and method for determining the coagulation status of a liquid, the device comprising a chamber for holding a quantity of blood sample, a magnetic bender body disposed in the chamber and a magnetic device being arranged in use to provide the first and second magnetic fields. The first magnetic field causes the bender body to move in a first direction within the chamber through uncoagulated liquid, and the second magnetic field causing the body to move in a second direction within the chamber through uncoagulated liquid. (see example 1). Wu does not specifically recite that the cross-section area of the bender body measured in a plane generally perpendicular to its normal direction of travel in use is at least half that of the chamber in the same plane. However, Wu teaches that the purpose of the magnetic bender body is to mix the plasma sample with an appropriate reagent (see Col.5, lines 3-6). The efficiency of mixing the plasma sample with the reagent depends on the cross-section area of the bender body and the space between the edge of the bender body and the wall of the chamber that holds the sample. Theses parameters can be optimized by routine experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, it would have been obvious to one of ordinary skill in the art to optimize the cross-section area of the bender body and the space between the bender body and the chamber wall to achieve better mixing efficiency.

As has been discussed in regard to Claim 26, Wu discloses that the magnetic bender body in the chamber is attached onto a piezoelectric film which is fixably attached at one end to the chamber wall (see Figure 2). This is an obvious variation to

"a body disposed in the chamber but not fixably attached to the chamber" as recited in the instant claim.

Wu discloses one magnetic device which generates two magnetic fields (see Col. 5, line 1-6, Figure 2). This is an obvious variation to "the first and second magnetic device being arranged in use to provide first and second magnetic fields" as recited in the instant claim.

In regard to Claims 29 and 43, Wu discloses that a 300 µl plasma sample was delivered onto the sample well in the test strip for both sample strip and control strip. The free volume in the instant claim when chamber contains the body is less that 10 µl., The free volume in the sample chamber equals the total volume of the chamber minus the volume of the bender body. The volume of the bender body and the free volume left in the chamber can affect the mixing efficiency of the sample with the reagent. Theses parameters can be optimized by routine experimentation. As has been discussed with respect to Claim 40, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, it would have been obvious to one of ordinary skill in the art to optimize the volume of the bender body and the free volume left in the chamber in order to achieve better mixing efficiency.

In regard to Claim 41, Wu discloses that through the attachment of the piezo film to the magnetic bender, movement of the magnetic bender is detected by measuring electric signal generated at the piezo film characterized by its frequency and amplitude due to movement of the attached metal film (see Col. 5 lines 12-16).

In regard to Claim 44, Wu discloses that the chamber is formed in a disposable strip (see Col. 5, lines 62-67; Col. 6, line 1-4).

In regard to Claim 45, Wu discloses that the chamber having the magnetic bender is elongated and has substantially uniform cross-section (see Figure 1 and 2).

In regard to Claims 32 and 46, Wu discloses that the reaction chamber is 0.5x1.5" in size and 0.005" in thickness (see Col. 6, lines 27-31). The length of the chamber in the instant claim is between 3 and 5 mm. As has been discussed in respect

to Claim 40, in order to achieve better mixing efficiency, the length of the chamber can be optimize by routine experimentation. Therefore, it would have been obvious for one of ordinary skill in the art to optimize the length of the chamber to achieve better mixing efficiency.

In regard to Claims 33 and 47, Wu discloses that the magnetic bender body is elongated (see Figure 2). Wu does not specifically recite that the bender has a cross-section of substantially the same shape as the cross-section of the chamber. However, solely based on the drawing of the Figure 2, one cross-section of the bender body has similar shape as the cross-section of the chamber. Similar shape of the bender body may increase the efficiency of mixing. At the time of the invention, it would have been obvious for one of ordinary skill in the art to select similar shape for the bender body.

In regard to Claims 34, 35, 48 and 49, Wu does not specifically recite the clearance between the bender body and walls of the chamber. As has been discussed in respect to Claim 40, in order to achieve better mixing efficiency, the relative clearance between the bender body and the walls of the chamber can be optimized by routine experimentation. Therefore, at the time of the invention, it would have been obvious for one of ordinary skill in the art to optimize the relative clearance between the bender body and the walls of the chamber to achieve better mixing result.

In regard to Claims 36, 37, 50, and 51, Wu does not specifically recite the length of the bender body movement. As has been discussed in respect to Claim 40, the length of the chamber and bender body and the resulting moving distance of bender body within the chamber can be optimized by routine experimentation to achieve better mixing efficiency. At the time of the invention, it would have been obvious to one of ordinary skill in the art to optimize the length of the chamber and body and the resulting moving distance of the bender body within the chamber to achieve better mixing efficiency.

In regard to Claim 52, Wu teaches that the bender body comprises an iron-based material, which experiences a force when placed in a magnetic field (see Col.4, lines 60-63).

In regard to Claim 53, Wu discloses that a clotting reagent is disposed in the chamber (see Col. 5, lines 38-42).

In regard to Claim 55, Wu discloses using an AC excitation generator coil to produce an AC electromagnetic field. The AC electromagnetic field cyclically provides a first and a second magnetic field. The first magnetic field drives an iron-based magnetic bender to move in a first direction and the second magnetic field drives the magnetic bender body to move in a second direction, the second direction is opposite to the first direction (see Col. 4, line 66-67; Col. 5, line 1-6).

In regard to Claim 56, it is known that the AC electromagnetic fields such as the one disclosed by Wu generally has the profile of Sines. The Sines profile has short pulse in each direction and with zero field strength between the pulses.

In regard to Claim 57, Wu discloses that the duration of each pulse is 0.005-0.5 ms (1-10 kHz) (see Col. 5, lines 9-12).

In regard to Claims 58 and 67, Wu discloses the frequency of the electromagnetic field is 1 to 100 kHz (see Col. 5, line 9-12). Therefore, the magnetic body under the field should move at this frequency. The frequency in Wu's device is higher than the frequency in the instant claim. The frequency of the magnetic body move to and fro within the chamber depends on the distance the magnetic body moves and the area of the cross-section of the magnetic body. These parameters can be optimized by routine experimentation to achieve better mixing efficiency. At the time of the invention, it would have been obvious to one of ordinary skill in the art to optimize the frequency of the magnetic body movement to achieve a better result.

In regard to Claims 59 and 68, Wu does not recite the magnitude of the electromagnetic field. The right magnitude of the electromagnetic field depends on the mass of the magnetic body and how fast it moves. At the time of the invention, it would have been obvious to one of ordinary skill in the art to optimize the magnitude of the magnetic field by routine experimentation to achieve the better mixing result.

In regard to Claim 64, Wu discloses using an AC excitation generator coil to produce an AC electromagnetic field. The AC electromagnetic field cyclically provides a first and a second magnetic field. The first magnetic field drives an iron-based magnetic

bender to move in a first direction and the second magnetic field drives the magnetic bender body to move in a second direction, the second direction is opposite to the first direction (see Col. 4, line 66-67; Col. 5, line 1-6).

In regard to Claim 65, it is known that the AC electromagnetic fields such as the one disclosed by Wu generally has the profile of Sines. The Sines profile has short pulse in each direction and with zero field strength between the pulses.

In regard to Claim 66, Wu discloses that the duration of each pulse is 0.005-0.5 ms (see Col. 5, lines 9-12).

In regard to Claim 70, Wu discloses that a clotting reagent is disposed in the chamber (see Col. 5, lines 38-42).

In regard to Claims 71 and 72, Wu does not disclose the first and second magnetic devices disposed on opposite sides of the chamber and been coaxial. Wu discloses one magnetic device which generates two magnetic fields (see Col. 5, line 1-6, Figure 2). The arrangement of the two magnetic devices to generate two magnetic fields would have been obvious variation to a single magnetic device that generates two magnetic fields as in Wu's design.

8. **Claims 28, 42, 60 and 62** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in view of Griebeler (US Patent No. 5,315,244).

In regard to Claims 28, 42, 60, 69, Wu teaches using electronic sensor to detect the movement of the bender body. Wu does not teach using magnetic field sensor to detect the movement of the bender body. The applicant is advised that the Supreme Court recently clarified that a claim can be proved obvious merely by showing that use of known technique to improve similar devices (methods, or products) in the same way (See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007)) (see MPEP § 2143).

In this regard, Griebeler teaches magnetic sensor for measuring the position, velocity and /or direction of movement of an object (see abstract). Wu discloses the similar device as the device in the instant claim. Both devices use magnetic field to move a body back and forth inside a reaction chamber to mix the blood sample with reagent. The mere difference is that Wu uses electronic sensor to detect the movement

of the body, and the instant claim uses magnetic sensor to detect the movement of the body. Both electronic sensor taught by Wu and magnetic sensors taught by GRIBELLER are known techniques at the time of the invention. Using of known technique (magnetic sensor) to improve similar device (device for determining the coagulation status of a blood sample) in the same way (detecting the movement of the mixing body) would have been obvious to one of ordinary skill in the art.

In regard to Claim 62, Wu discloses a method of determining the coagulation status of a blood sample disposed in a chamber (see abstract). The bender body comprises an iron-based material which experiences a force when placed in the first and second magnetic fields (see Col.4, lines 60-63). The first magnetic field causes the body to move in a first direction within the chamber through uncoagulated liquid, and the second magnetic field causing the body to move in a second direction within the chamber (see Col. 5, line 1-6).

Wu teaches using electronic sensor to detect the movement of the bender body. Wu does not teach using magnetic field sensor to detect the movement of the bender body. As has been discussed in respect to claims 28, 42, and 60 above, using of known technique (magnetic sensor) to improve similar device (device for determining the coagulation status of a blood sample) in the same way (detecting the movement of the mixing body) would have been obvious to one of ordinary skill in the art.

As has been discussed in regard to Claim 26, Wu discloses that the magnetic bender body in the chamber is attached onto a piezoelectric film which is fixably attached at one end to the chamber wall (see Figure 2). This is an obvious variation to "a body not fixably attached to the chamber" as recited in the instant claim.

Response to Arguments

9. Applicant's arguments filed on 05/11/2009 have been fully considered but they are not persuasive.

Applicants argue that the piezoelectric film and bender of Wu are fixably attached to the chamber. The question is whether the difference between Wu and the instant claim would have been an obvious modification. Wu discloses a magnetic bender body

in a chamber attached onto a piezoelectric film which is fixably attached at one end to the chamber wall (see Figure 2). Wherein, the two magnetic fields cause the bender body moving (vibrating) in two directions. In the instant claim, the body is not fixably attached to the chamber. Wherein, the two magnetic fields cause the body moving in two directions. Based on these circumstances, the difference would have been minor or obvious, unless applicants can show that the modification generated unexpected results over Wu.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT XU whose telephone number is (571)270-5560. The examiner can normally be reached on Mon-Thur 7:30am-5:00pm, Fri 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

5/15/2009

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

RX